Office of Research and Development
DEPARTMENT OF VETERANS AFFAIRS

Fact Sheet — July 2003

New Policy Will Help VAMCs Cover Compliance Costs

Forty percent of Veterans Affairs (VA) research involving human subjects is funded by pharmaceutical companies or other industry sponsors. When simple chart reviews are excluded, the figure reaches eighty percent. A recent review of VA research participant protection indicated the need for increased quality assurance by VA and highlighted the responsibility of industry to help cover the costs of human-subjects protection.

To address the first issue, VA's Office of Research and Development (ORD) has implemented new programs to strengthen ongoing quality assurance at every VA research site. One major change is the implementation of a "hub and spoke" model wherein regional compliance offices will work closely with local VA medical centers (VAMCs) in a proactive, team-oriented manner to provide training, education and guidance and to anticipate problems before they occur.

To address the second issue, VA has instituted a new facility human protections program (FHPP) policy to help VAMCs defray the costs of protecting veterans in industry-sponsored studies. This policy (VA directive 2003-31) was issued June 13, 2003 and became effective July 1, 2003.

Background

- The cost of compliance activities, such as training and credentialing of VA research staff, is estimated to be about 10 percent of the direct costs of industry-sponsored studies. This estimate does not include Institutional Review Board (IRB) expenses.
- The vast majority of industry-sponsored research grants conducted at VAMCs are administered by either the university affiliate or by one of the VA-affiliated nonprofit research corporations.

Key points of the new policy:

- This policy applies only to new, VA-approved studies that are funded by industry and that involve human subjects.
- All affiliates and nonprofit corporations that administer industry-sponsored grants will make available 10 percent of direct study costs, or a flat fee of $1,200, whichever is greater, to help the participating VAMC cover compliance costs associated with human subjects protection. (the minimum fee may be waived by ORD in certain circumstances.)
- At a minimum, the ACOS/R will ensure that for any studies, there is written acknowledgement from the study administrator that 10% of the direct cost of the studies will be made available to the participating VAMC on an annualized basis.
- The FHPP funds can be accrued by the study administrator over a period of one year.
- The portion of these funds not needed for compliance activities may be applied to other research costs.
- The facility Research and Development Office will report annually to ORD: the total number of industry –sponsored studies conducted at that VAMC, the total amount of direct costs of industry-funded studies conducted at that VAMC, an accounting of all expenditures in support of compliance-related activities and the amount of support made available to the VAMC by each study administrator.
- This policy does not apply to IRB related costs, which should continue to be covered separately.